

STATUTORY INSTRUMENTS SUPPLEMENT
to The Uganda Gazette No. 55, Volume CXIV, dated 2nd July, 2021

Printed by UPPC, Entebbe, by Order of the Government.

S T A T U T O R Y I N S T R U M E N T S

2021 No. 42.

**THE NATIONAL DRUG POLICY AND AUTHORITY (LICENSING)
(AMENDMENT) REGULATIONS, 2021**

ARRANGEMENT OF REGULATIONS

Regulation

1. Title
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3. Amendment of Regulation 9 of principal Regulations
4. Amendment of Regulation 11 of principal Regulations
5. Amendment of Regulation 16 of principal Regulations
6. Amendment of Regulation 18 of principal Regulations
7. Amendment of Regulation 25 of principal Regulations
8. Insertion of regulation 30A in principal Regulations
9. Insertion of regulation 30B in principal Regulations
10. Saving and transitional provisions.
11. Amendment of Schedule to principal Regulations

STATUTORY INSTRUMENTS

2021 No. 42.

The National Drug Policy and Authority (Licensing) (Amendment) Regulations, 2021

*(Under section 64 of the National Drug Policy and Authority Act,
Cap. 206)*

IN EXERCISE of the powers conferred upon the Minister responsible for health by section 64 of the National Drug Policy and Authority Act, and on the advice of the National Drug Authority, these Regulations are made this 16th day of June, 2021.

1. Title

These Regulations may be cited as the National Drug Policy and Authority (Licensing) (Amendment) Regulations, 2021.

2. Amendment of S.I No. 35 of 2014

The National Drug Policy and Authority (Licensing) Regulations, 2014, in these Regulations referred to as the principal Regulations are amended in regulation 5, by numbering the provision as (1) and inserting after subregulation (1) the following subregulation –

“(2) A licence to sell Class C drugs shall be in the format prescribed in Form 16A in the Schedule to these Regulations.”

3. Amendment of Regulation 9

Regulation 9 of the principal Regulations is amended by revoking subregulation (2) and subregulation (3).

4. Amendment of Regulation 11

Regulation 11 of the principal Regulations, is amended by numbering the provision as (1) and inserting after subregulation (1) the following subregulations—

“(2) A licence to operate a retail pharmacy shall be in the format prescribed in Form 17A in the Schedule to these Regulations.

(3) Notwithstanding subregulation (1), the Authority shall not issue a licence to operate a retail pharmacy, except where the distance of that pharmacy from an existing pharmacy complies with subregulation (4).

(4) The distance, from any direction, between a pharmacy for which an application for a licence is made under this regulation and any existing retail pharmacy, located in an area specified in the first column in the Table in this subregulation, shall not be less than the distance prescribed in the second column.

Location	Distance in meters
Kampala Capital City	300
City	300
Municipality	150
Town Council	100
Rural areas	100”

5. Amendment of Regulation 16

Regulation 16 of the principal Regulations is amended by inserting immediately after subregulation (3), the following—

“(4) A licence to operate a wholesale pharmacy shall be in the format prescribed in Form 18A in the Schedule to these Regulations.”

(5) Notwithstanding subregulation (1), the Authority shall not issue a licence to operate a wholesale pharmacy, except where the distance of that pharmacy from an existing pharmacy complies with subregulation (6).

(6) The distance, from any direction, between a pharmacy for which an application for a licence is made under this regulation and any existing wholesale pharmacy, located in an area specified in the first column in the Table in this subregulation, shall not be less than the distance prescribed in the second column.

Location	Distance in meters
Kampala Capital City	300
City	300
Municipality	150
Town Council	100
Rural areas	100"

6. Amendment of Regulation 18.

Regulation 18 of the principal Regulations is amended by inserting immediately after subregulation (2), the following subregulations –

“(3) The Authority shall issue a license to manufacture drugs where the applicant complies with the requirements of subregulations (1) and (2).

(4) A licence to manufacture drugs shall be in the format prescribed in Form 19A in the Schedule to these Regulations.”

7. Amendment of Regulation 25

Regulation 25 principal Regulations is amended by inserting immediately after subregulation (1) the following—

“(1A) An application for renewal of a licence for a wholesale pharmacy, retail pharmacy or a licensed seller shall be made at least three months before the expiry of the licence.”

8. Insertion of regulation 30A

The principal Regulations are amended, by inserting immediately after regulation 30, the following—

“30A. Relocation of the business premises of a licensed seller, retail pharmacy and wholesale pharmacy.

(1) A licensed seller, retail pharmacy or wholesale pharmacy that seeks to relocate to other premises may do so as prescribed in this regulation.

(2) A licensed seller, retail pharmacy or wholesale pharmacy may —

(a) relocate to other premises located at distance of two hundred meters or less, from the current premises of that licensed seller, retail pharmacy or wholesale pharmacy; or

(b) in accordance with the requirements of subregulation (3), relocate to other premises located at distance of more than two hundred meters from the current premises of that licensed seller, retail pharmacy or wholesale pharmacy.

(3) For the purposes of subregulation (2) (b), the distance, from any direction, between a licensed seller, retail pharmacy or wholesale pharmacy referred to that subregulation and any existing licensed seller, retail pharmacy or wholesale pharmacy, located in an area specified in the first column in the Table in this subregulation, shall not be less than the distance prescribed in the second column.

Location	Distance in meters
Kampala Capital City	200
City	200

Municipality	150
Town Council	100
Rural areas	100

(4) A licensed seller, retail pharmacy or wholesale pharmacy that seeks to relocate to other premises, shall make an application for relocation to the Authority and shall attach the licence to operate as a licensed.

(5) person or licensed seller, as the case may be, issued by the Authority.

(6) For the avoidance of doubt—

- (a) a licensed seller, retail pharmacy or wholesale pharmacy shall make an application for relocation after a period of twelve months from the date of issue of a licence; and
- (b) a licensed seller, retail pharmacy or wholesale pharmacy that previously relocated, shall only make application for another relocation after a period of twelve months from the date of the previous relocation.”

9. Insertion of regulation 30B

The principal Regulations are amended, by inserting immediately after regulation 30A, the following—

“30B. Conversion of licensed seller into retail pharmacy.

(1) A licensed seller that seeks to convert into a retail pharmacy may do so as prescribed in this regulation.

(2) A licensed seller that seeks to convert into a retail pharmacy—

- (a) may do so at the current premises of that licensed seller, where those premises meet the standards prescribed in Part I of the National Drug Policy and Authority (Suitability of Premises) Regulations, 2014;
- (b) shall, where the current premises of that licensed seller do not meet the standards prescribed in Part I of the National Drug Policy and Authority (Suitability of Premises) Regulations, 2014—
 - (i) relocate to any premises located at a distance of two hundred meters or less, from any direction, from the current premises of that licensed seller; or
 - (ii) in accordance with the requirements of subregulation (3), relocate to any premises located at distance of more than two hundred meters from the current premises of that licensed seller.

(3) For the purposes of subregulation (2)(b), the distance, from any direction, between the licensed seller referred to in subregulation (1) and any existing retail pharmacy, located in an area specified in the first column in the Table in this subregulation, shall not be less than the distance prescribed in the second column.

Location	Distance
Kampala Capital City	200
City	200
Municipality	150
Town Council	100
Other areas	100

(7) A licensed seller that seeks to convert into a retail pharmacy shall make an application to the Authority and shall attach the licence to operate as a licensed seller, issued by the Authority.

10. Saving and transitional provisions.

(1) A licence in force at the commencement of these Regulations shall continue in force until the licence expires or is cancelled, in accordance with these Regulations.

(2) Regulation 9(1) of the principal Regulations shall not apply to a person who is issued with a licence to operate as a licensed seller, before the commencement of these Regulations.

(3) Regulation 4 of these Regulations shall not apply to an application for a licence to operate a retail pharmacy, that is received by the Authority before the commencement of these Regulations.

(4) Regulation 8 of these Regulations shall not apply to an application for relocation that is received by the Authority before the commencement of these Regulations.

11. Amendment of Schedule

The Schedule to the principal Regulations is amended—

- (a) by inserting immediately after Form 16 the following Form 16A—

DRUG

NATIONAL



AUTHORITY

LICENSE TO OPERATE AS A LICENSED SELLER

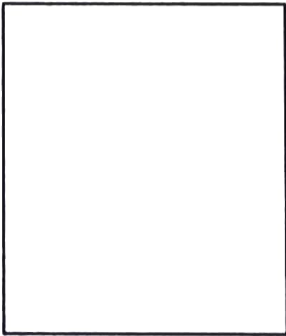
This is to certify that

.....
is licensed for the retail sale of Class C Drugs only and NOT Class A or B Drugs

at:.....(*physical location*)

and Supervising by Full-time In-charge:.....

Photograph of In-charge



Licence No:.....

Issue Date:Valid up to:.....



.....
FOR THE AUTHORITY

This license must be prominently displayed in the premises for which it is issued”

(b) by inserting immediately after Form 17 the following Form 17A –

“FORM 17A

Regulation 11 (2)



LICENSE TO OPERATE RETAIL PHARMACY

This is to certify that

.....
is licensed to operate a Retail Pharmacy

at:..... *(physical location)*

Postal Address:.....

TIN :.....

.....

Premise No:.....

Issue Date:Valid up to:.....



.....
FOR THE AUTHORITY

This license must be prominently displayed in the premises for which it is issued”

(c) by inserting immediately after Form 18 the following Form 18A—

“FORM 18A

Regulation 16 (4)

DRUG



NATIONAL

AUTHORITY

LICENSE TO OPERATE WHOLESALE PHARMACY

This is to certify that

.....
is licensed to operate a Wholesale Pharmacy

at : *(physical location)*

Postal Address:

TIN :

Premise No.....

Issue Date Valid up to



.....
FOR THE AUTHORITY

This license must be prominently displayed in the premises for which it is issued”

(d) by inserting immediately after Form 19 the following Form 19A

“FORM 19A

Regulation 18 (4)

DRUG

NATIONAL



AUTHORITY

LICENSE TO MANUFACTURE DRUGS

This is to certify that

.....
at (physical location)
and Postal Address.....

TIN :
is authorized to carry out the following manufacturing activities for the corresponding product category and dosage forms;

Dosage form	Product category	Manufacturing activities

Premise No.....

Issue Date Valid up to



.....
FOR THE AUTHORITY

This license must be prominently displayed in the premises for which it is issued”

HON. DR. ACENG JANE RUTH OCERO,
Minister for Health.